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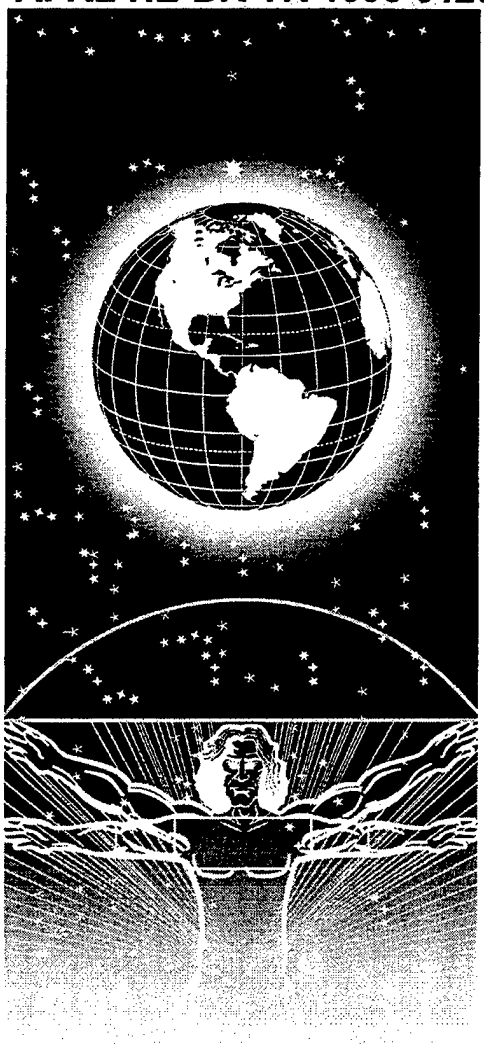

UNITED STATES AIR FORCE RESEARCH LABORATORY

TESTING AND EVALUATION OF THE MINE SAFETY APPLIANCES, CO., MODEL 3000 OXYGEN MONITOR

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December 1998

NOTICES

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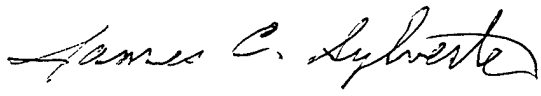

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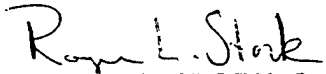

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The Mine Safety Appliances, Co., Model 3000, Oxygen Monitor is an oxygen monitor designed to provide continuous, direct monitoring of oxygen mixtures. The unit operates on a 9V internal battery. The unit weighs approximately 260 Gm or 9.2 oz. and is 3.25 in. W. X 5.98 in. H. X 1.31 in. D.

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ACKNOWLEDGMENTS

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TESTING AND EVALUATION OF THE MINE SAFETY APPLIANCES, CO., MODEL 3000 OXYGEN MONITOR

BACKGROUND

The Mine Safety Appliances company (MSA) requested Aeromedical Research's participation in evaluating and approving their model 3000, oxygen monitor for use on board USAF aeromedical evacuation aircraft. Specific components of the model 3000, oxygen monitor that under went the evaluation process included the model 3000, oxygen monitor basic unit (P/N 814365), oxygen sensor (P/N 406931), mounting bracket (P/N 474664), coiled cable (P/N 472045), tee adapter (P/N 473021), and restraining strap (P/N 634249). All components of the model 3000, oxygen monitor were tested for air worthiness. Throughout this report the term "Equipment Under Test" (EUT) refers to the model 3000, oxygen monitor.

DESCRIPTION

The EUT is an oxygen monitor designed to provide continuous, direct monitoring of oxygen mixtures. The unit operates on a 9V internal battery. The unit weighs approximately 260 Gm or 9.2 oz. and is 3.25 in. W. X 5.98 in. H. X 1.31 in. D. (Figure 1)

Figure 1. MSA 3000, Oxygen Monitor

PROCEDURES

Test methods and performance criteria were derived from nationally recognized performance guidelines (1 & 2), various military standards (3-8), and manufacturer's literature (9). The Aeromedical Research Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (10). A test setup and performance check was developed specific to this EUT to verify its proper functioning under various testing conditions. All tests are conducted by Aeromedical Research personnel assigned to the Systems Research Branch (HEPR), Biodynamics and Protection Division, Air Force Research Laboratory, Brooks AFB, Texas., unless otherwise noted.

The EUT was subjected to various laboratory and inflight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection

2. Vibration

3. Electromagnetic Interference (EMI)

4. Thermal/ Humidity Environmental Conditions, encompassing:

    a. Hot Operation

    b. Cold Operation

    c. Humidity Operation

    d. Hot Temperature Storage

    e. Cold Temperature Storage

5. Hypobaric Conditions

    a. Cabin Pressure/Altitude

    b. Rapid Decompression to Ambient Pressure

6. Airborne Performance

INITIAL INSPECTION AND TEST PREPARATION

a. The EUT was inspected for quality of workmanship, production techniques and pre-existing damage.

b. The EUT was checked to ensure it met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99 (1); AFI 41-203, Electrical Shock Hazards (3); and AFI 41-201, Equipment Management in Hospitals (4). Ground resistance and leakage current measurements were made at 115 VAC/60 Hz and 115 VAC/400 Hz.

c. The EUT was examined to ensure it met basic requirements for human factor design as outlined in MIL-STD 1472 (5).

d. A test setup and performance check was developed to evaluate the EUT's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

Placed EUT on a level surface with EUT powered by internal 9V battery; connected coiled cable to EUT; connected other end of coiled cable to oxygen sensor; placed oxygen sensor into Tee adapter; turned unit on. (Depending on test, EUT was left exposed to ambient conditions or 100% oxygen was run to Tee adapter at 15/lpm.)

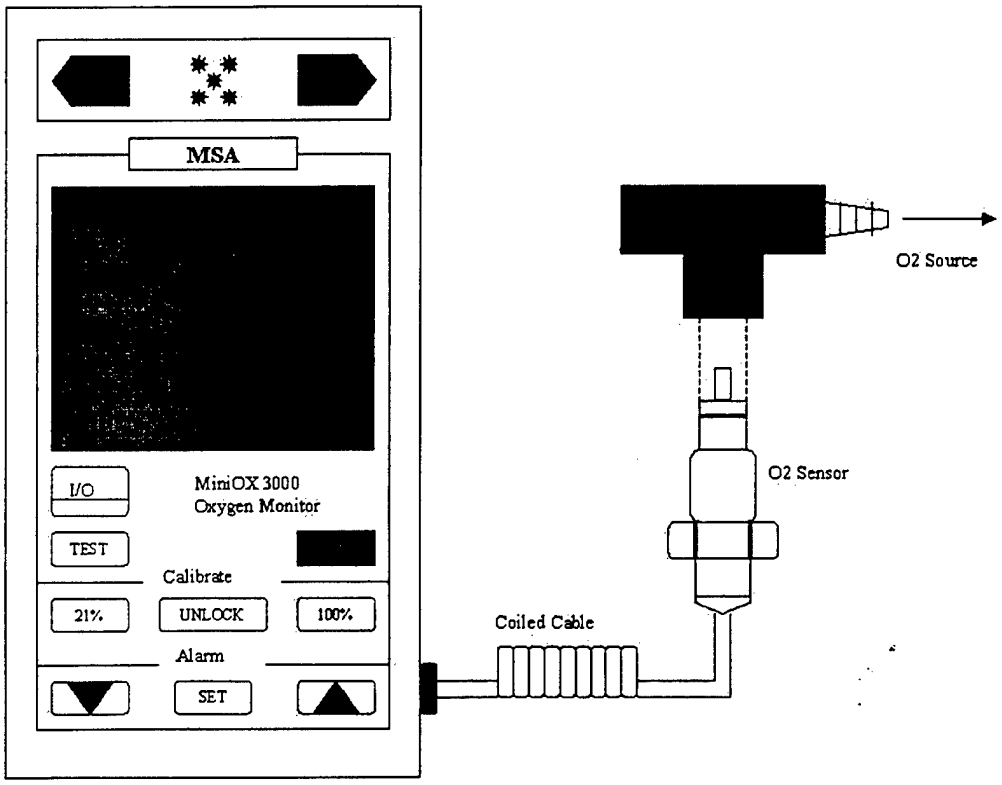

Figure 2. Test Setup

PERFORMANCE CHECK

The following performance check was used to validate the function of the EUT during each of the following test conditions:

Coiled cable was connected to receptacle on the right side of EUT and the other end to the oxygen sensor. Turn EUT on; once CAL screen is visible press either 21% or 100%, then press unlock. This will start the cal sequence. Note: when assessing ambient oxygen concentrations press 21% button after CAL screen is visible. If assessing 100% attach oxygen source to Tee adapter and free flow oxygen through Tee adapter throughout cal sequence.

To check EUT alarms, press alarm set button after EUT has completed the cal sequence, to adjust input values use the arrow buttons on either side of alarm set button.

VIBRATION

Vibration testing is critical to determine "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (6). Testing was conducted on an Unholtz-Dickey Corporation Vibration Test System, amplifier model SA30 and shaker model R16W. This testing involved a set of operational tests performed along each of three axes - X, Y, and Z. The EUT's components were mounted on a NATO litter segment on the vibration table, as it would be secured in the aircraft (Figure 3). They were subjected to vibration curves with similar intensities and durations as those derived from MIL-STD-810E, Category 10, Figures 514.4-16 and 514.4-17 (Figure 4).

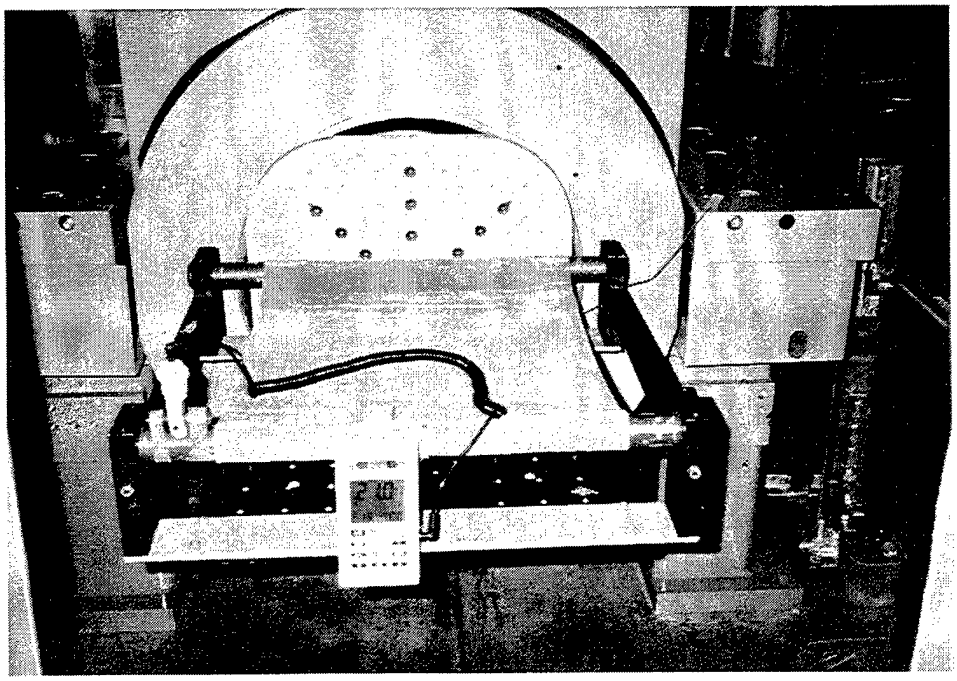

Figure 3. Vibration Table Mounting

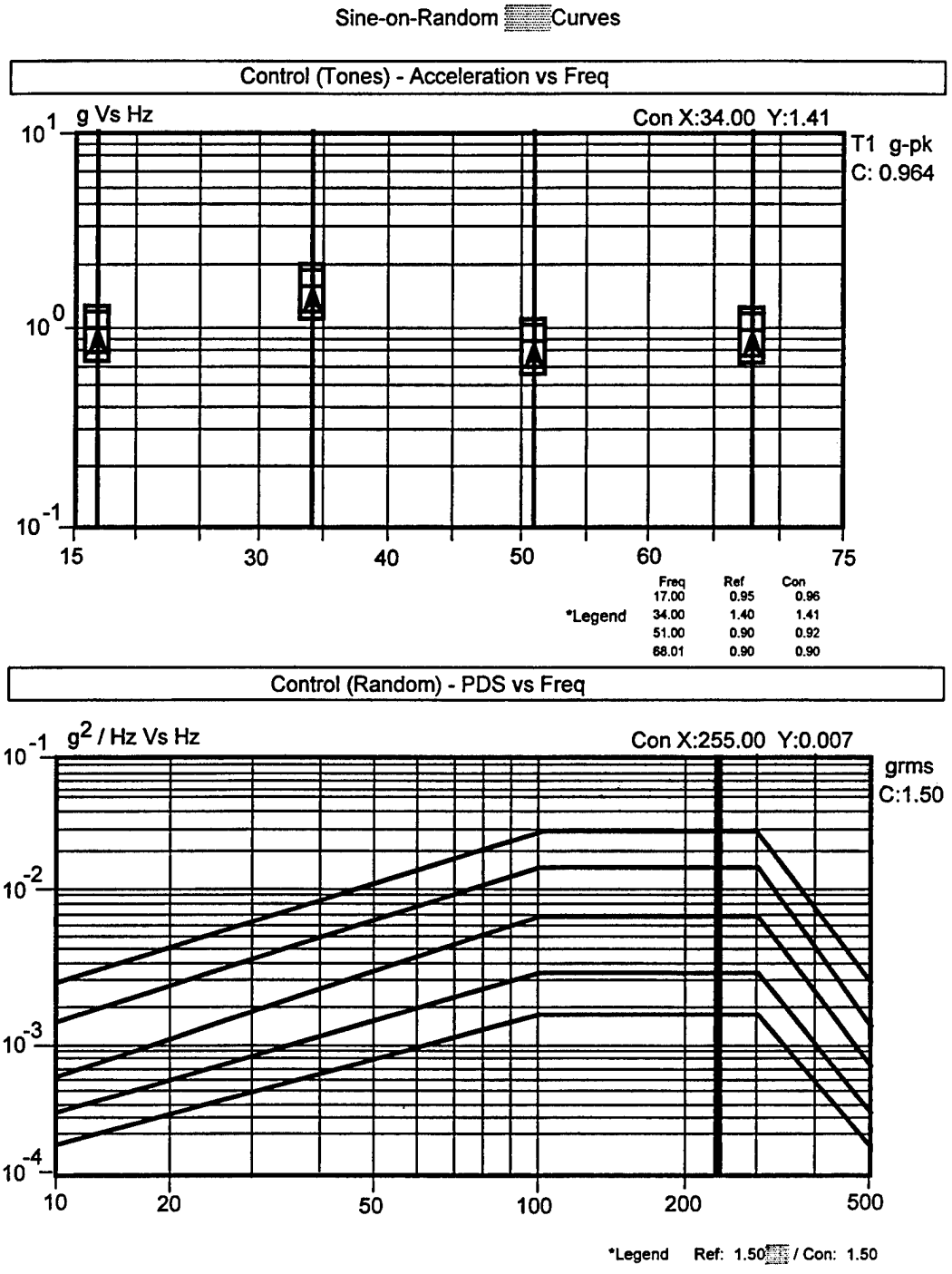

Figure 4. MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility testing is a primary concern on USAF aeromedical evacuation aircraft. Safety is the driving factor to assessing the effects of excessive electromagnetic emissions and potential influence on aircraft navigation and communications

equipment. Medical devices may be susceptible to fields generated by aircraft equipment and malfunction in their presence.

The EUT was evaluated for compliance with MIL-STD-461D & MIL-STD-462D (7 & 8). ASC/ENAI engineers at Wright-Patterson AFB evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

a. Radiated Emissions (RE-102), "Radiated Emissions, Electric Field, 10 kHz to 18 GHz.": For Air Force aircraft applications, radiated emissions were tested in a narrower range of frequencies from 2 MHz - 1 GHz. This test measured the amount of EMI emitted by the EUT during operation. It verifies the EUT's potential to affect other equipment susceptible to electromagnetic emissions (i.e., aircraft navigation and communications equipment).

b. Radiated Susceptibility (RS-103), "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz.": For Air Force aircraft applications, radiated susceptibility was tested in a narrower frequency range from 30 MHz - 12.4 GHz at the following field strength levels: 20 V/M below 1 GHz and 60 V/M above 1 GHz (MIL-STD-461D field strength values from Table IV, Category Aircraft Internal). This test evaluated the EUT's resistance to predefined levels of EMI generated by antennas both internal and external to the aircraft.

c. Conducted Susceptibility (CS-114), "Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 400 MHz.": For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout the frequency band from 10 kHz to 200 MHz. This test determined whether "simulated currents that will be developed on platform cabling from electromagnetic fields generated by antenna transmission would affect the equipment under test."

d. Conducted Susceptibility (CS-115), "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation": This test was performed to ensure the EUT could withstand the "fast rise and fall time that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse."

e. Conducted Susceptibility (CS-116), "Conducted Susceptibility, Damped Sinusoidal Transients, Cables and Power Leads, 10 kHz - 100 MHz," respectively. The "basic concept of this test is to simulate electrical current and voltage waveforms occurring in platforms from excitation of natural resonances." During emissions testing, all EUT's electrical components were operating for the duration of the test to create the worst case emissions scenario. In these tests, the EUT operated in the 21% mode. For susceptibility testing, the EUT was operated again in the 21% mode. For both emissions and susceptibility testing, the EUT was tested for operation on 115 VAC / 60, 400 Hz, and internal batteries.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

Extreme temperature and humidity testing determines if aeromedical equipment can be stored and operated during severe environmental conditions without experiencing physical damage or deterioration in performance (6). Extreme environmental conditions can have incapacitating effects on medical equipment including the following; changes in material characteristics and material dimensions, overheating, changes in electronic components, and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in the Air Force Research Laboratory's Thermotron Industries, model SM-32 environmental chamber. The EUT was placed in the center of the environmental chamber. All input and output cables and wires were routed through a port in the chamber wall, which was subsequently sealed with a precut sponge plug. The other components of the test setup remained outside the chamber. For operational tests, the EUT was monitored continuously, and a performance check was conducted every 15 minutes. For storage tests, the EUT was placed in the chamber and remained nonoperational throughout the storage portion of the test. The following describes the conditions of the environmental tests performed:

a. Humidity: 94 ± 4% RH, 85°F ± 3.6°F (29.5°C ± 2°C) for 4 hr

b. Hot Temp Operation: 120°F ± 3.6°F (49°C ± 2°C) for 2 hr

c. Cold Temp Operation: 32°F ± 7.2°F (0°C ± 4°C) for 2 hr

d. Hot Temp Storage: 140°F ± 3.6°F (60°C ± 2°C) for 6 hr

e. Cold Temp Storage: -40°F ± 3.6°F (-40°C ± 2°C) for 6 hr

HYPOBARIC CONDITIONS

Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to potential effects of barometric pressure changes on the equipment. A majority of the aircraft characterized as opportune aircraft available for use in aeromedical evacuation pressurize their cabin atmosphere to barometric pressures equivalent to 8,000-10,000 ft above sea level. The differences in pressures affect the operation of some medical equipment. Altitude testing consisted of operating the EUT while ascending from ground level to 10,000 ft; stopping at 2,000 ft increments for performance checks; and then descending back to ground again stopping at 2,000 ft increments for performance checks. The rates of ascent and descent were 5,000 ft/min.

Rapid Decompression Testing: A rapid decompression (RD) is the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressures. It is important to assess medical equipment functioning during and after RD so as not to endanger patients, personnel, or the aircraft. The EUT operated inside the rapid decompression test chamber as the chamber was pressurized to an equivalent of 8,000 ft altitude. The chamber

altitude was then brought to 45,000 ft over a period of 60 seconds, held at 45,000 ft for a few minutes, and then returned to ground at a rate of 10,000-12,000 ft/min. The test was repeated twice more; once for a 7-second RD and once for a 1-second RD. The EUT was monitored throughout the series of decompressions; performance checks were assessed each time the unit returned to ground level.

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating clinical and operational suitability under actual operating conditions. By carefully evaluating medical equipment items in their proposed operational environment, Aeromedical Research verifies demonstrations of all pertinent patient care issues are adequately addressed by the test protocols. Safe and reliable operation is the primary goal of the inflight evaluation and forms the basis for subsequent recommendations to the users.

This phase of testing was conducted by qualified aeromedical crewmembers from Aeromedical Research on C-141B aeromedical evacuation missions. The EUT was positioned and secured to a NATO litter using it's own securing bracket and evaluated. Human factor characteristics, securing methods, setup/tear down times and securing locations were also evaluated. Feedback from other aeromedical evacuation crew members participating in delivery of patient care was obtained concerning EUT human factor considerations.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed no manufacturing defects. The unit performed to the manufacturer's specification.

VIBRATION

The EUT performed according to manufacturer specifications.

ELECTROMAGNETIC COMPATIBILITY

ASC/ENAI, Wright-Patterson AFB certified the EUT for use in aeromedical evacuation system on all U.S. Air Force aircraft while operating from 9V-battery power.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The EUT experienced minor deviations during thermal testing (Hot & Cold operation). Once the EUT was recalibrated it maintained accurate readings throughout the remainder of the test cycle. During humidity evaluation the EUT had a similar experience. The unit was recalibrated and readings remained accurate throughout test cycles. Due to manufacturer's guidelines (See note) and EUT's ability to recover following recalibration, Aeromedical Research staff found the unit to be acceptable for use onboard all USAF aircraft.

*Note: Manufacturer operating limits for thermal extremes is 0° C to 40° C or 32° F to 104°F. For humidity, the operations manual states that the presence of humidity decreases actual concentration of oxygen and condensation build up may block flow of oxygen across the sensor. Users should follow manufacturer's guidance when troubleshooting the unit.

HYPOBARIC CONDITIONS

1. Cabin Pressure/Altitude: The EUT performed in accordance with manufacturer's specifications throughout testing.

2. Rapid Decompression: The EUT operated satisfactorily following each decompression.

AIRBORNE PERFORMANCE

The inflight evaluation of the EUT was performed on a C-141 aeromedical evacuation mission. Evaluation confirmed that the unit would operate successfully during all phases of flight. Analysis of performance data indicated this unit was easy to enplane and deplane and was compatible with aircraft electrical systems. It is recommended that the securing bracket provided by the manufacturer be used to secure the unit. This bracket is made to secure the unit to the litter pole on a standard NATO litter.

SUMMARY

Aeromedical Research found the Mine Safety Appliances, Co., model 3000 oxygen monitor to be acceptable for use on all U.S. Air Force aeromedical evacuation aircraft (including small and large body, fixed and rotary wing) while operating on 9V battery power. The EUT operated IAW manufacturer's specifications, minor unit degradation noted. With the above validation complete, further evaluation of the EUT's operation was within expected parameters when subjected to environmental extremes, simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. The following recommendations apply:

REFERENCES

1. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code
2. Emergency Care Research Institute (ECRI)
3. AFI 41-203, Electrical Shock Hazards
4. AFI 41-201, Equipment Management in Hospitals
5. MIL-STD 1472, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.
6. MIL-STD 810E, Environmental Test Methods and Engineering Guidelines.
7. MIL-STD 461D, Electromagnetic Emission and Susceptibility Requirements for the Control Of Electromagnetic Interference.
8. MIL-STD-462 D, Measurement of EMI Characteristics.
9. Mine Safety Appliances, Co., Model 3000, Oxygen Monitor, Operations & Service Manual.
10. Aeromedical Research Procedures Guide, Internal Operating Instruction, Systems Research Branch, Armstrong Laboratory.

APPENDIX
MANUFACTURER'S SPECIFICATIONS OF MINE SAFETY APPLIANCES, CO., MODEL 3000 OXYGEN MONITOR

SPECIFICATIONS

General

Size	3.26 in. W. X 5.98 in. H. X 1.31 in. D.
Weight	260 Gm or 9.2 oz.
Power	One 9-volt replaceable battery.
Environmental	Temperature: 0°C to 40°C (operating). -40°C to 70°C (storage and shipping). Humidity: 5 - 95% (non condensing).
Sensor Life	Over one year in normal medical conditions
Sensor Self Life	Six months minimum (stored in sealed package)